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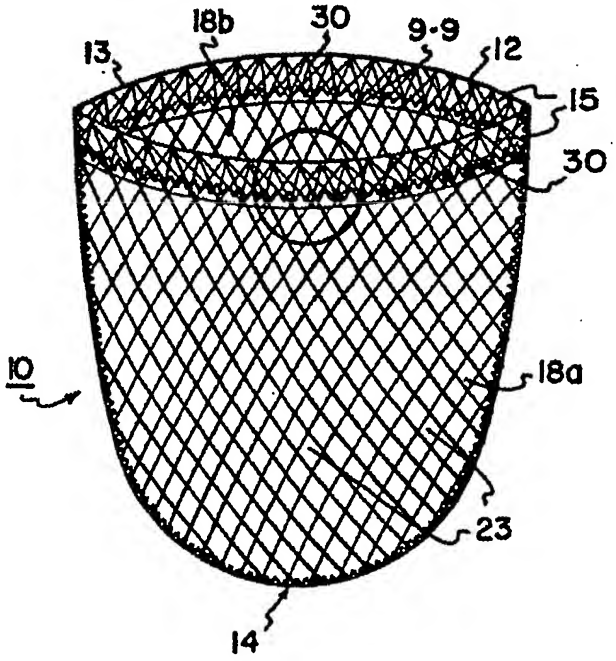
(54) Title: CARDIAC CONSTRAINT JACKET CONSTRUCTION

(57) Abstract

A jacket is for placement over a heart to constrain congestive heart failure related expansion includes a biocompatible fabric formed into a pouch having a base end and an apical end with an interior of the pouch sized to receive a patient's heart. The base end has a peripheral edge defining a base opening sized to pass an apex of the heart through the base opening. The heart is slipped into the interior of the pouch with the apical end facing the apex of the heart and with the base end facing toward the base of the heart. At the base end, the fabric is folded over for the peripheral edge to have at least a double layer of the fabric. The double layer terminates at a free edge on an outer surface of the pouch and is spaced from the peripheral edge. In an additional embodiment, the fabric includes a side edge of opposing fabric surfaces extending from the apical end to the base end. The opposing fabric surfaces are joined by a stitch assembly. The stitch assembly includes a first stitch line spaced from free edges of the surfaces to define a junction of the fabric surfaces. The free edges are folded back onto the fabric surfaces to define at least a double layer of fabric on opposite sides of the junction. A second stitch line is placed over the junction and through the double layers on the opposite sides of the junction.



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CARDIAC CONSTRAINT JACKET CONSTRUCTION

I.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention pertains to a method for treating heart disease by placing a cardiac constraint jacket around the heart to constrain expansion. More particularly, the present invention is directed to a novel construction of such a jacket.

2. Description of the Prior Art

Congestive heart failure is a progressive and debilitating illness. The disease is characterized by a progressive enlargement of the heart.

As the heart enlarges, the heart is performing an increasing amount of work in order to pump blood each heart beat. In time, the heart becomes so enlarged the heart cannot adequately supply blood. An afflicted patient is fatigued, unable to perform even simple exerting tasks and experiences pain and discomfort. Further, as the heart enlarges, the internal heart valves cannot adequately close. This impairs the function of the valves and further reduces the heart's ability to supply blood.

Causes of congestive heart failure are not fully known. In certain instances, congestive heart failure may result from viral infections. In such cases, the heart may enlarge to such an extent that the adverse consequences of heart enlargement continue after the viral infection has passed and the disease continues its progressively debilitating course.

Patients suffering from congestive heart failure are commonly grouped into four classes (i.e., Classes I, II, III and IV as defined by the New York Heart Association – NYHA). In the early stages (e.g., Classes I and II), drug therapy is the commonly proscribed treatment. Drug therapy treats the symptoms of the disease and may slow the progression of the disease. Importantly, there is no cure for congestive heart failure. Even with drug therapy, the disease will progress. Further, the drugs may have adverse side effects.

Presently, the only proven permanent treatment for congestive heart failure is heart transplant. To qualify, a patient must be in the later stage of the disease (e.g.,

Classes III and IV with Class IV patients given priority for transplant). Such patients are extremely sick individuals. Class III patients have marked physical activity limitations and Class IV patients are symptomatic even at rest.

Due to the absence of effective intermediate treatment between drug therapy and heart transplant, Class III and IV patients will have suffered terribly before qualifying for heart transplant. Further, after such suffering, the available treatment is unsatisfactory. Heart transplant procedures are very risky, extremely invasive and expensive and only shortly extend a patient's life. For example, prior to transplant, a Class IV patient may have a life expectancy of 6 months to one-year. Heart transplant may improve the expectancy to about five years.

Unfortunately, not enough hearts are available for transplant to meet the needs of congestive heart failure patients. In the United States, in excess of 35,000 transplant candidates compete for only about 2,000 transplants per year. A transplant waiting list is about 8 – 12 months long on average and frequently a patient may have to wait about 1 – 2 years for a donor heart. While the availability of donor hearts has historically increased, the rate of increase is slowing dramatically. Even if the risks and expense of heart transplant could be tolerated, this treatment option is becoming increasingly unavailable. Further, many patients do not qualify for heart transplant for failure to meet any one of a number of qualifying criteria.

Congestive heart failure has an enormous societal impact. In the United States alone, about five million people suffer from the disease (Classes I through IV combined). Alarmingly, congestive heart failure is one of the most rapidly accelerating diseases (about 400,000 new patients in the United States each year). Economic costs of the disease have been estimated at $38 billion annually.

Not surprising, substantial effort has been made to find alternative treatments for congestive heart failure. Recently, a new surgical procedure has been developed. Referred to as the Batista procedure, the surgical technique includes dissecting and removing portions of the heart in order to reduce heart volume. This is a radical new and experimental procedure subject to substantial controversy. Furthermore, the procedure is highly invasive, risky and expensive and commonly includes other expensive procedures (such as a concurrent heart valve replacement). Also, the

treatment is principally limited to Class IV patients and, accordingly, provides no hope to patients facing ineffective drug treatment prior to Class IV. Finally, if the procedure fails, emergency heart transplant is the only available option.

Clearly, there is a need for alternative treatments applicable to both early and later stages of the disease to either stop the progressive nature of the disease or more drastically slow the progressive nature of congestive heart disease. Unfortunately, currently developed options are experimental, costly and problematic.

Cardiomyoplasty is a recently developed treatment for earlier stage congestive heart disease (e.g., as early as Class III dilated cardiomyopathy). In this procedure, the latissimus dorsi muscle (taken from the patient's shoulder) is wrapped around the heart and chronically paced synchronously with ventricular systole. Pacing of the muscle results in muscle contraction to assist the contraction of the heart during systole.

Even though cardiomyoplasty has demonstrated symptomatic improvement, studies suggest the procedure only minimally improves cardiac performance. The procedure is highly invasive requiring harvesting a patient's muscle and an open chest approach (i.e., sternotomy) to access the heart. Furthermore, the procedure is expensive -- especially those using a paced muscle. Such procedures require costly pacemakers. The cardiomyoplasty procedure is complicated. For example, it is difficult to adequately wrap the muscle around the heart with a satisfactory fit. Also, if adequate blood flow is not maintained to the wrapped muscle, the muscle may necrose. The muscle may stretch after wrapping reducing its constraining benefits and is generally not susceptible to post-operative adjustment. Finally, the muscle may fibrose and adhere to the heart causing undesirable constraint on the contraction of the heart during systole.

While cardiomyoplasty has resulted in symptomatic improvement, the nature of the improvement is not understood. For example, one study has suggested the benefits of cardiomyoplasty are derived less from active systolic assist than from remodeling, perhaps because of an external elastic constraint. The study suggests an elastic constraint (i.e., a non-stimulated muscle wrap or an artificial elastic sock placed around the heart) could provide similar benefits. Kass et al., *Reverse Remodeling From Cardiomyoplasty In Human Heart Failure: External Constraint*

Versus Active Assist, 91 Circulation 2314 – 2318 (1995). Similarly, cardiac binding is described in Oh et al., *The Effects of Prosthetic Cardiac Binding and Adynamic Cardiomyoplasty in a Model of Dilated Cardiomyopathy*, 116 J. Thorac. Cardiovasc. Surg. 148 – 153 (1998), Vaynblat et al., *Cardiac Binding in Experimental Heart Failure*, 64 Ann. Thorac. Surg. 81 – 85 (1997) and Capouya et al., *Girdling Effect of Nonstimulated Cardiomyoplasty on Left Ventricular Function*, 56 Ann. Thorac. Surg. 867 – 871 (1993).

In addition to cardiomyoplasty, mechanical assist devices have been developed as intermediate procedures for treating congestive heart disease. Such devices include left ventricular assist devices ("LVAD") and total artificial hearts ("TAH"). An LVAD includes a mechanical pump for urging blood flow from the left ventricle and into the aorta. Such surgeries are expensive. The devices are at risk of mechanical failure and frequently require external power supplies. TAH devices are used as temporary measures while a patient awaits a donor heart for transplant.

Commonly assigned U.S. Patent No. 5,702,343 to Alferness dated December 30, 1997 teaches a jacket to constrain cardiac expansion during diastole. Also, PCT International Publication No. WO 98/29401 published July 9, 1998 teaches a cardiac constraint in the form of surfaces on opposite sides of the heart with the surfaces joined together by a cable through the heart or by an external constraint. U.S. Pat. No. 5,800,528 dated September 1, 1998 teaches a passive girdle to surround a heart. Commonly assigned and copending U.S. patent application Ser. No. 09/114,757 filed July 13, 1998 teaches a cardiac constraint device in the form of a knit pouch of open cell fabric. It is an object of the present invention to provide a novel and improved construction of a cardiac constraint device such as that shown in the '757 application.

II.

SUMMARY OF THE INVENTION

According to a preferred embodiment of the present invention, a jacket is disclosed for placement over a heart to constrain congestive heart failure related expansion. The jacket includes a biocompatible fabric formed into a pouch having a base end and an apical end with an interior of the pouch sized to receive a patient's

heart. The base end has a peripheral edge defining a base opening sized to pass an apex of the heart through the base opening. The heart is slipped into the interior of the pouch with the apical end facing the apex of the heart and with the base end facing toward a base of the heart. At the base end, the fabric is folded over for the peripheral edge to have at least a double layer of the fabric. The double layer terminates at an edge on an outer surface of the pouch and is spaced from the peripheral edge. In an additional embodiment, the fabric includes a side edge of opposing fabric surfaces extending from the apical end to the base end. The opposing fabric surfaces are joined by a stitch assembly. The stitch assembly includes a first stitch line spaced from free edges of the surfaces to define a junction of the fabric surfaces. The free edges are folded back onto the fabric surfaces to define at least a double layer of fabric on opposite sides of the junction. A second stitch line is placed over the junction and through the double layers on the opposite sides of the junction.

III.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic cross-sectional view of a normal, healthy human heart shown during systole;

Fig. 1A is the view of Fig. 1 showing the heart during diastole;

Fig. 2 is a schematic cross-sectional view of a diseased human heart shown during systole;

Fig. 2A is the view of Fig. 2 showing the heart during diastole;

Fig. 3 is a perspective view of a cardiac constraint device to be used according to the method of the present invention;

Fig. 3A is a side elevation view of a diseased heart in diastole with the device of Fig. 3 in place;

Fig. 4 is a perspective view of an alternative cardiac constraint device to be used according to the method of the present invention;

Fig. 4A is a side elevation view of a diseased heart in diastole with the device of Fig. 4 in place;

Fig. 5 is a cross-sectional view of the device of Fig. 3 overlying a myocardium and with the material of the device gathered for a snug fit;

Fig. 6 is an enlarged view of a knit construction of the device of the present invention in a rest state;

Fig. 7 is a schematic view of the material of Fig. 6;

Fig. 8 is a perspective view of a jacket constructed according to the present invention;

Fig. 9 is an enlarged view of an area of Fig. 8 contained within circle 9-9 of Fig. 8;

Fig. 10 is a view taken along line 10-10 in Fig. 9;

Fig. 11 is an exploded perspective view of two sheets of fabric to be joined according to the construction of the present invention to form the jacket of Fig. 8;

Fig. 12 is a plan view, partly in section, of the two sheets of Fig. 11 in overlying relation with a side edge of the sheets joined by a first straight stitching;

Fig. 13 is a view taken along Fig. 13-13 in Fig. 12;

Fig. 14 is a plan view of a side edge of the sheets of Fig. 12 after application of a second zigzag stitching; and

Fig. 15 is a view taken along line 15-15 in Fig. 14.

IV.

DESCRIPTION OF THE PREFERRED EMBODIMENT

A. Congestive Heart Failure

To facilitate a better understanding of the present invention, description will first be made of a cardiac constraint device such as is more fully described in commonly assigned and copending U.S. patent application Ser. No. 09/114,757 filed July 13, 1998. In the drawings, similar elements are labeled similarly throughout.

With initial reference to Figs. 1 and 1A, a normal, healthy human heart H' is schematically shown in cross-section and will now be described in order to facilitate an understanding of the present invention. In Fig. 1, the heart H' is shown during systole (i.e., high left ventricular pressure). In Fig. 1A, the heart H' is shown during diastole (i.e., low left ventricular pressure).

The heart H' is a muscle having an outer wall or myocardium MYO' and an internal wall or septum S'. The myocardium MYO' and septum S' define four internal heart chambers including a right atrium RA', a left atrium LA', a right

ventricle RV' and a left ventricle LV'. The heart H' has a length measured along a longitudinal axis BB' – AA' from an upper end or base B' to a lower end or apex A'.

The right and left atria RA', LA' reside in an upper portion UP' of the heart H' adjacent the base B'. The right and left ventricles RV', LV' reside in a lower portion LP' of the heart H' adjacent the apex A'. The ventricles RV', LV' terminate at ventricular lower extremities LE' adjacent the apex A' and spaced therefrom by the thickness of the myocardium MYO'.

Due to the compound curves of the upper and lower portions UP', LP', the upper and lower portions UP', LP' meet at a circumferential groove commonly referred to as the A-V groove AVG'. Extending away from the upper portion UP' are a plurality of major blood vessels communicating with the chambers RA', RV', LA', LV'. For ease of illustration, only the superior vena cava SVC', inferior vena cava IVC' and a left pulmonary vein LPV' are shown as being representative.

The heart H' contains valves to regulate blood flow between the chambers RA', RV', LA', LV' and between the chambers and the major vessels (e.g., the superior vena cava SVC', inferior vena cava IVC' and a left pulmonary vein LPV'). For ease of illustration, not all of such valves are shown. Instead, only the tricuspid valve TV' between the right atrium RA' and right ventricle RV' and the mitral valve MV' between the left atrium LA' and left ventricle LV' are shown as being representative.

The valves are secured, in part, to the myocardium MYO' in a region of the lower portion LP' adjacent the A-V groove AVG' and referred to as the valvular annulus VA'. The valves TV' and MV' open and close through the beating cycle of the heart H.

Figs. 1 and 1A show a normal, healthy heart H' during systole and diastole, respectively. During systole (Fig. 1), the myocardium MYO' is contracting and the heart assumes a shape including a generally conical lower portion LP'. During diastole (Fig. 1A), the heart H' is expanding and the conical shape of the lower portion LP' bulges radially outwardly (relative to axis AA' – BB').

The motion of the heart H' and the variation in the shape of the heart H' during contraction and expansion is complex. The amount of motion varies considerably throughout the heart H'. The motion includes a component which is

parallel to the axis AA' – BB' (conveniently referred to as longitudinal expansion or contraction). The motion also includes a component perpendicular to the axis AA'-BB' (conveniently referred to as circumferential or radial expansion or contraction).

Having described a healthy heart H' during systole (Fig. 1) and diastole (Fig. 1A), comparison can now be made with a heart deformed by congestive heart failure. Such a heart H is shown in systole in Fig. 2 and in diastole in Fig. 2A. All elements of diseased heart H are labeled identically with similar elements of healthy heart H' except only for the omission of the apostrophe in order to distinguish diseased heart H from healthy heart H'.

Comparing Figs. 1 and 2 (showing hearts H' and H during systole), the lower portion LP of the diseased heart H has lost the tapered conical shape of the lower portion LP' of the healthy heart H'. Instead, the lower portion LP of the diseased heart H bulges outwardly between the apex A and the A-V groove AVG. So deformed, the diseased heart H during systole (Fig. 2) resembles the healthy heart H' during diastole (Fig. 1A). During diastole (Fig. 2A), the deformation is even more extreme.

As a diseased heart H enlarges from the representation of Figs. 1 and 1A to that of Figs. 2 and 2A, the heart H becomes a progressively inefficient pump. Therefore, the heart H requires more energy to pump the same amount of blood. Continued progression of the disease results in the heart H being unable to supply adequate blood to the patient's body and the patient becomes symptomatic insufficiency.

For ease of illustration, the progression of congestive heart disease has been illustrated and described with reference to a progressive enlargement of the lower portion LP of the heart H. While such enlargement of the lower portion LP is most common and troublesome, enlargement of the upper portion UP may also occur.

In addition to cardiac insufficiency, the enlargement of the heart H can lead to valvular disorders. As the circumference of the valvular annulus VA increases, the leaflets of the valves TV and MV may spread apart. After a certain amount of enlargement, the spreading may be so severe the leaflets cannot completely close. Incomplete closure results in valvular regurgitation contributing to an additional degradation in cardiac performance. While circumferential enlargement of the

valvular annulus VA may contribute to valvular dysfunction as described, the separation of the valve leaflets is most commonly attributed to deformation of the geometry of the heart H.

B. Cardiac Constraint Therapy

Having described the characteristics and problems of congestive heart disease, a treatment method and apparatus are described in commonly assigned and copending U.S. patent application 09/114,757 filed July 13, 1998. In general, a jacket is configured to surround the myocardium MYO. While the method of the present invention will be described with reference to a jacket as described in commonly assigned and copending U.S. patent application Ser. No. 09/114,757 filed July 13, 1998, it will be appreciated the present invention is applicable to any cardiac constraint device including those shown in U.S. Pat. No. 5,800,528 and PCT International Publication No. WO 98/29401.

With reference now to Figs. 3, 3A, 4 and 4A, the cardiac constraint device is shown as a jacket 10, 10' of flexible, biologically compatible material. The jacket 10, 10' is an enclosed knit material having upper and lower ends 12, 12' and 14. The jacket 10, 10' defines an internal volume 16, 16' which is completely enclosed but for the open ends 12, 12' and 14'. In the embodiment of Fig. 3, lower end 14 is closed. In the embodiment of Fig. 4, lower end 14' is open. In both embodiments, upper ends 12, 12' are open. Throughout this description, the embodiment of Fig. 3 will be discussed. Elements in common between the embodiments of Figs. 3 and 4 are numbered identically with the addition of an apostrophe to distinguish the second embodiment and such elements need not be separately discussed.

The jacket 10 is dimensioned with respect to a heart H to be treated. Specifically, the jacket 10 is sized for the heart H to be constrained within the volume 16. The jacket 10 can be slipped around the heart H. The jacket 10 has a length L between the upper and lower ends 12, 14 sufficient for the jacket 10 to constrain the lower portion LP. The upper end 12 of the jacket 10 extends at least to the valvular annulus VA and further extends to the lower portion LP to constrain at least the lower ventricular extremities LE.

When the parietal pericardium is opened, the lower portion LP is free of obstructions for applying the jacket 10 over the apex A. If, however, the parietal pericardium is intact, the diaphragmatic attachment to the parietal pericardium inhibits application of the jacket over the apex A of the heart. In this situation, the jacket can be opened along a line extending from the upper end 12' to the lower end 14' of jacket 10'. The jacket can then be applied around the pericardial surface of the heart and the opposing edges of the opened line secured together after placed on the heart. Systems for securing the opposing edges are disclosed in, for example, U.S. Patent No. 5,702,343, the entire disclosure of which is incorporated herein by reference. The lower end 14' can then be secured to the diaphragm or associated tissues using, for example, sutures, staples, etc.

In the embodiment of Figs. 3 and 3A, the lower end 14 is closed and the length L is sized for the apex A of the heart H to be received within the lower end 14 when the upper end 12 is placed at the A-V groove AVG. In the embodiment of Figs. 4 and 4A, the lower end 14' is open and the length L' is sized for the apex A of the heart H to protrude beyond the lower end 14' when the upper end 12' is placed at the A-V groove AVG. The length L' is sized so that the lower end 14' extends beyond the lower ventricular extremities LE such that in both of jackets 10, 10', the myocardium MYO surrounding the ventricles RV, LV is in direct opposition to material of the jacket 10, 10'. Such placement is desirable for the jacket 10, 10' to present a constraint against enlargement of the ventricular walls of the heart H.

After the jacket 10 is positioned on the heart H as described above, the jacket 10 is secured to the heart. Preferably, the jacket 10 is secured to the heart H through sutures. The jacket 10 is sutured to the heart H at suture locations S circumferentially spaced along the upper end 12. While a surgeon may elect to add additional suture locations to prevent shifting of the jacket 10 after placement, the number of such locations S is preferably limited so that the jacket 10 does not restrict contraction of the heart H during systole.

To permit the jacket 10 to be easily placed on the heart H, the volume and shape of the jacket 10 are larger than the lower portion LP during diastole. So sized, the jacket 10 may be easily slipped around the heart H. Once placed, the jacket's volume and shape are adjusted for the jacket 10 to snugly conform to the external

geometry of the heart H during diastole. Such sizing is easily accomplished due to the knit construction of the jacket 10. For example, excess material of the jacket 10 can be gathered and sewn together with sutures S" (Fig. 5) to reduce the volume of the jacket 10 and conform the jacket 10 to the shape of the heart H during diastole. Such shape represents a maximum adjusted volume. The jacket 10 constrains enlargement of the heart H beyond the maximum adjusted volume while preventing restricted contraction of the heart H during systole. As an alternative to gathering of Fig. 5, the jacket 10 can be provided with other ways of adjusting volume. For example, as disclosed in U.S. Patent No. 5,702,343, the jacket can be provided with a slot. The edges of the slot can be drawn together to reduce the volume of the jacket.

The jacket 10 is adjusted to a snug fit on the heart H during diastole. Care is taken to avoid tightening the jacket 10 too much such that cardiac function is impaired. During diastole, the left ventricle LV fills with blood. If the jacket 10 is too tight, the left ventricle LV cannot adequately expand and left ventricular pressure will rise. During the fitting of the jacket 10, the surgeon can monitor left ventricular pressure. For example, a well-known technique for monitoring so-called pulmonary wedge pressure uses a catheter placed in the pulmonary artery. The wedge pressure provides an indication of filling pressure in the left atrium LA and left ventricle LV. While minor increases in pressure (e.g., 2 – 3 mm Hg) can be tolerated, the jacket 10 is snugly fit on the heart H but not so tight as to cause a significant increase in left ventricular pressure during diastole.

As mentioned, the jacket 10 is constructed from a knit, biocompatible material. The knit 18 is illustrated in Fig. 6. Preferably, the knit is a so-called "Atlas knit" well known in the fabric industry. The Atlas knit is described in Paling, Warp Knitting Technology, p. 111, Columbine Press (Publishers) Ltd., Buxton, Great Britain (1970).

The Atlas knit is a knit of fibers 20 having directional expansion properties. More specifically, the knit 18, although formed of generally inelastic fibers 20, permits a construction of a flexible fabric at least slightly expandable beyond a rest state. Fig. 6 illustrates the knit 18 in a rest state. Shown in a simplified schematic in Fig. 7, the fibers 20 of the fabric 18 are woven into two sets of fiber strands 21a, 21b

having longitudinal axes X_a and X_b. The strands 21a, 21b are interwoven to form the fabric 18 with strands 21a generally parallel and spaced-apart and with strands 21b generally parallel and spaced-apart.

For ease of illustration, fabric 18 is schematically shown in Fig. 7 with the axis of the strands 21a, 21b only being shown. The strands 21a, 21b are interwoven with the axes X_a and X_b defining a diamond-shaped open cell 23 having diagonal axes A_m. In a preferred embodiment, the axes A_m are approximately 2 mm in length when the fabric 18 is at rest and not stretched. The fabric 18 can stretch in response to a force. For any given force, the fabric 18 stretches most when the force is applied parallel to the diagonal axes A_m. The fabric 18 stretches least when the force is applied parallel to the strand axes X_a and X_b. The jacket 10 is constructed for the material of the knit to be directionally aligned for a diagonal axis A_m to be parallel to the heart's longitudinal axis AA-BB

While the jacket 10 is expandable due to the above-described knit pattern, the yarn or fibers 20 (which are multi-filament fibers) of the knit 18 are preferably non-expandable. In response to the low pressures in the heart H during diastole, the fibers 20 are non-elastic. In a preferred embodiment, the fibers are 70 Denier polyester. While polyester is presently preferred, other suitable materials include polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE) or polypropylene.

The knit material has numerous advantages. Such a material is flexible to permit unrestricted movement of the heart H (other than the desired constraint on circumferential expansion). The material is open defining a plurality of interstitial spaces for fluid permeability as well as minimizing the amount of surface area of direct contact between the heart H and the material of the jacket 10 (thereby minimizing areas of irritation or abrasion) to minimize fibrosis and scar tissue.

The open areas of the knit construction also allows for electrical connection between the heart and surrounding tissue for passage of electrical current to and from the heart. For example, although the knit material is an electrical insulator, the open knit construction is sufficiently electrically permeable to permit the use of trans-chest defibrillation of the heart. Also, the open, flexible construction permits passage of electrical elements (e.g., pacer leads) through the jacket. Additionally, the open construction permits other procedures, e.g., coronary bypass, to be

performed without removal of the jacket. If desired, the jacket material can be cut after placement of the jacket to provide greater access for such procedures.

A large open area for cells 23 is desirable to minimize the amount of surface area of the heart H in contact with the material of the jacket 10 (thereby reducing fibrosis). However, if the cell area 23 is too large, localized aneurysms can form. Also, a strand 21a, 21b lying over a coronary vessel may result in sufficient force to partially block the vessel. A smaller cell size increases the number of strands thereby decreasing the restricting force per strand. Preferably, a maximum cell area is no greater than about 6.45 cm^2 (about 2.54 cm by 2.54 cm) and, more preferably, is about 9 mm^2 (about 3 mm by 3 mm). The maximum cell area is the area of a cell 23 after the material of the jacket 10 is fully stretched and adjusted to the maximum adjusted volume on the heart H as previously described.

The fabric 18 is preferably tear and run resistant. In the event of a material defect or inadvertent tear, such a defect or tear is restricted from propagation by reason of the knit construction.

The jacket 10 constrains further undesirable circumferential enlargement of the heart while not impeding other motion of the heart H. With the benefits of the present teachings, numerous modifications are possible. For example, the jacket 10 need not be directly applied to the epicardium (i.e., outer surface of the myocardium) but could be placed over the parietal pericardium. Further, an anti-fibrosis lining (such as a PTFE coating on the fibers of the knit) could be placed between the heart H and the jacket 10. Alternatively, the fibers 20 can be coated with PTFE.

The jacket 10 can be used in early stages of congestive heart disease. For patients facing heart enlargement due to viral infection, the jacket 10 permits constraint of the heart H for a sufficient time to permit the viral infection to pass. In addition to preventing further heart enlargement, the jacket 10 treats valvular disorders by constraining circumferential enlargement of the valvular annulus and deformation of the ventricular walls.

C. Novel Jacket Construction

Having described a jacket 10 as taught in the '757 application, the novel construction of the present invention can now be described.

With reference to Figs. 8 – 15, the jacket 10 may be formed of two sheets of knit fabric 18a, 18b such as that disclosed above and with open cells 23 of the jacket 10 oriented as previously described. To prepare the jacket 10, the sheets 18a, 18b are placed overlying one another and side edges 19a, 19b (Fig. 13) of the sheets 18a, 18b are stitched together as will be more fully described.

At the peripheral edge 13 of the upper or base end 12, a portion 15 of the fabric 18a, 18b is folded over to form a double layer of material best illustrated in Figs. 9 and 10. If desired, multiple folds could be formed to have greater than two layers of fabric. The folded portion 15 opposes the outer surface 18c of the fabric and terminates at a free edge 15a, 15b spaced from the peripheral edge 13. At the free edge 15a, 15b, a stitch pattern 30 is placed to secure the free edge 15a, 15b to the opposing surface 18c of the fabric and to lock down the free edge. Preferably, the stitch pattern 30 is a zigzag pattern with one or more stitches per length of cells 23.

The folded portion 15 and zigzag stitch pattern 30 contribute to the performance of the jacket 10. As a result of this construction, a non-traumatic peripheral edge 13 rests against the heart. The double material layer at the folded portion 15 provides a reinforced area of material retaining similar compliance as the remainder of the jacket 10. Within this reinforced area, a surgeon may place sutures for attaching the jacket 10 to the heart. Further, the stitch pattern 30 presents a visually perceptible line to assist a surgeon in identifying the folded portion 15 as the preferred suturing site. The surgeon can also suture over the stitch pattern 30 for extra strength. The zigzag stitch pattern 30 permits the stitch pattern 30 to stretch with the fabric and not reduce the compliance of the jacket 10. In the embodiment of Fig. 4, a folded portion may also be provided at the apical edge. While a zigzag stitch pattern is presently preferred, any compliant stitch pattern may be used.

As previously mentioned, the sheets 18a, 18b (with stitched folded portions 15 as described above) are placed overlying one another and side edges 19a, 19b (Fig. 13) of the sheets 18a, 18b are stitched together. The stitching is performed in a two-step process. First, a straight stitch pattern 32 is made through the sheets 18a, 18b adjacent side edges 19a, 19b (Figs. 12 and 13). This straight stitch 32 defines a junction of the sheets 18a, 18b and results in two flaps 34a, 34b of excess material

between the junction and the edges 19a, 19b. The flaps 34a, 34b are folded back over the sheets 18a, 18b and a zigzag stitch pattern 36 is placed over the junction and through the flaps 34a, 34b and opposing sheets 18a, 18b (Figs. 14 and 15). Unstitched, excess material of the flaps 34a, 34b is then removed.

With the construction as thus described, the completed jacket 10 is formed. The benefits of the reinforced base end fold 15 have already been recited. The side stitching as described results in a flat seam of reduced bulk with minimized raised ridge. The smooth side of the side seam faces the heart. The seam is strong and stretches longitudinally. While not necessary, the fabric sheets 18a, 18b may be longitudinally stretched during application of the straight stitch 32. The sheets are permitted to relax during application of the zigzag stitch 36.

From the foregoing detailed description, the invention has been described in a preferred embodiment. Modifications and equivalents of the disclosed concepts are intended to be included within the scope of the appended claims. For example, the above description shows two separate sheets of material joined to form a jacket. A single sheet can be used folded over with a side stitch on only one side.

What is claimed is:

1. A jacket for placement over a heart to constrain congestive heart failure related expansion, said jacket comprising:

- a biocompatible fabric formed into a pouch having a base end and an apical end with an interior of the pouch sized to receive a patient's heart;
- the base end having a peripheral edge defining a base opening sized to pass an apex of the heart through the base opening to slip the pouch onto the heart with the heart received within the interior of the pouch and with the apical end facing the apex of the heart and with the base end facing toward a base of the heart; and
- the fabric at the base end folded over for the peripheral edge to have at least a double layer of the fabric and with the double layer terminating at a free edge on an outer surface of the pouch and spaced from the peripheral edge.

2. A jacket according to claim 1 wherein:

- the pouch has a longitudinal axis extending from the apical end to the base end and the fabric is stretchable in a direction transverse to the longitudinal axis;
- the double layer of the fabric is secured together in a manner to permit the double layer to stretch as the fabric of the pouch is stretched.

3. A jacket according to claim 2 wherein the free edge is stitched to an opposing surface of the fabric with a stretchable stitching pattern.

4. A jacket according to claim 3 wherein the stitching pattern is a zigzag pattern.

5. A jacket according to claim 4 wherein the fabric is a knit fabric having a plurality of open cells and the zigzag stitching pattern is spaced for at least one zigzag stitch per each cell.

6. A jacket according to claim 3 wherein the stitching pattern is applied with the base end stretched during application of the stitching pattern.

7. A jacket according to claim 1 wherein the fabric includes a side edge of opposing fabric surfaces extending from the apical end to the base end.

8. A jacket according to claim 7 wherein the opposing fabric surfaces are joined by stitch assembly including:

- a first stitch line spaced from free edges of the surfaces to define a junction of the fabric surfaces;
- the free edges are folded back onto the fabric surfaces to define at least a double layer of fabric on opposite sides of the junction; and
- a second stitch line is placed over the junction and through the double layers on the opposite sides of the junction.

9, A jacket according to claim 8 wherein the stitch assembly is stretchable.

10. A jacket according to claim 8 wherein the first stitch line is a straight stitch line and the second stitch line is a zigzag stitch line.

11. A jacket according to claim 10 wherein the first stitch line is placed when the fabric is at rest and the second stitch line is placed when the fabric is pre-stretched.

12. A jacket for placement over a heart to constrain congestive heart failure related expansion, said jacket comprising:

- a biocompatible fabric formed into a pouch having a base end and an apical end with an interior of the pouch sized to receive a patient's heart;
- the base end having a peripheral edge defining a base opening sized to pass an apex of the heart through the base opening to slip the pouch onto the heart with the heart received within the interior of the

pouch and with the apical end facing the apex of the heart and with the base end facing toward a base of the heart;

- the fabric includes at least one side edge of opposing fabric surfaces extending from the apical end to the base end and with the opposing fabric surfaces are joined by stitch assembly including:
  - a first stitch line spaced from free edges of the surfaces to define a junction of the fabric surfaces;
  - the free edges are folded back onto the fabric surfaces to define at least a double layer of fabric on opposite sides of the junction; and
  - a second stitch line is placed over the junction and through the double layers on the opposite sides of the junction.

13. A jacket according to claim 12 wherein the stitch assembly is stretchable.

14. A jacket according to claim 12 wherein the first stitch line is a straight stitch line and the second stitch line is a zigzag stitch line.

15. A jacket according to claim 14 wherein the first stitch line is placed when the fabric is at rest and the second stitch line is placed when the fabric is pre-stretched.

16. A jacket according to claim 12 wherein the fabric at the base end is folded over for the peripheral edge to have at least a double layer of the fabric and with the double layer terminating at a free edge on an outer surface of the pouch and spaced from the peripheral edge.

17. A jacket according to claim 16 wherein:

- the pouch has a longitudinal axis extending from the apical end to the base end and the fabric is stretchable in a direction transverse to the longitudinal axis;
- the double layer of the fabric is secured together in a manner to permit the double layer to stretch as the fabric of the pouch is stretched.

18. A jacket according to claim 17 wherein the free edge is stitched to an opposing surface of the fabric with a stretchable stitching pattern.

19. A jacket according to claim 18 wherein the stitching pattern is a zigzag pattern.

20. A jacket according to claim 19 wherein the fabric is a knit fabric having a plurality of open cells and the zigzag stitching pattern is spaced for at least one zigzag stitch per each cell.

21. A jacket according to claim 18 wherein the stitching pattern is applied with the base end stretched during application of the stitching pattern.

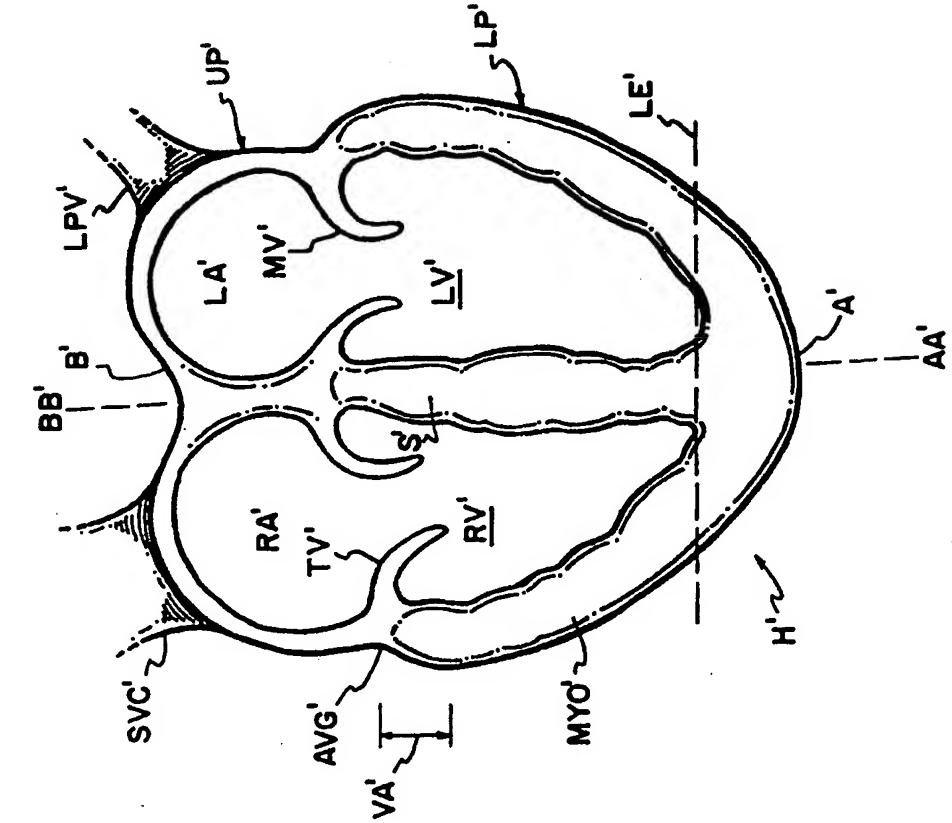
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FIG. 1A

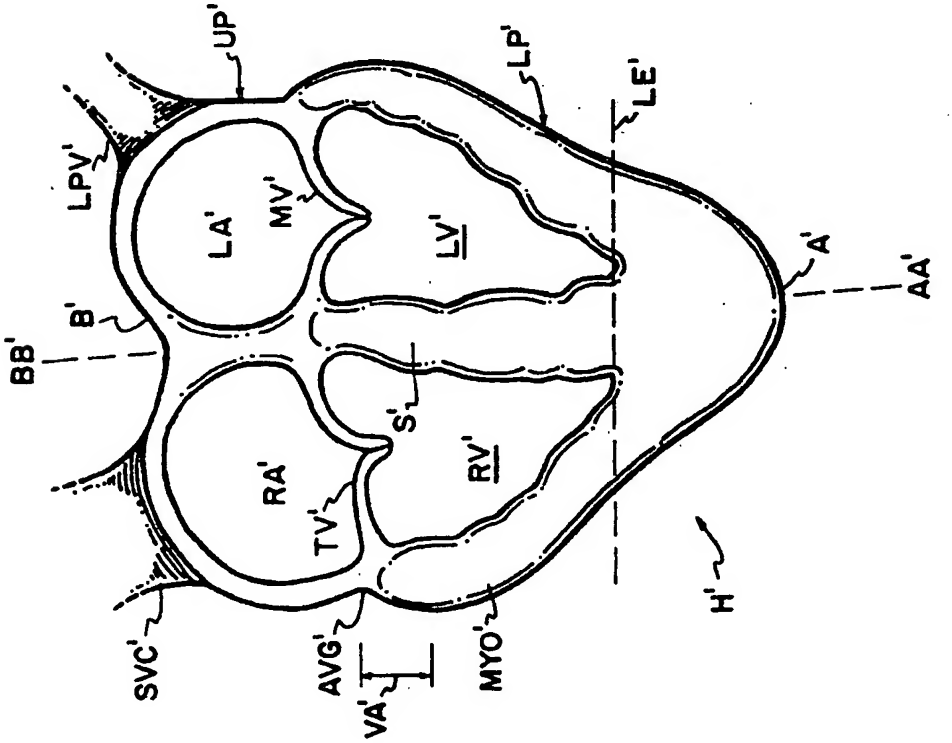
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FIG. 1

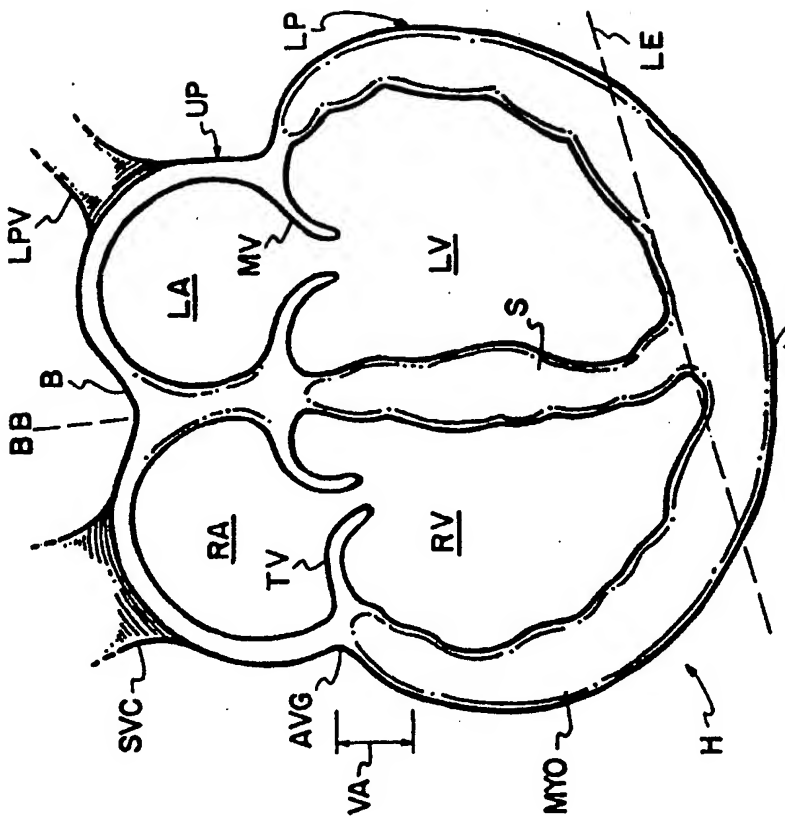
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FIG. 2A

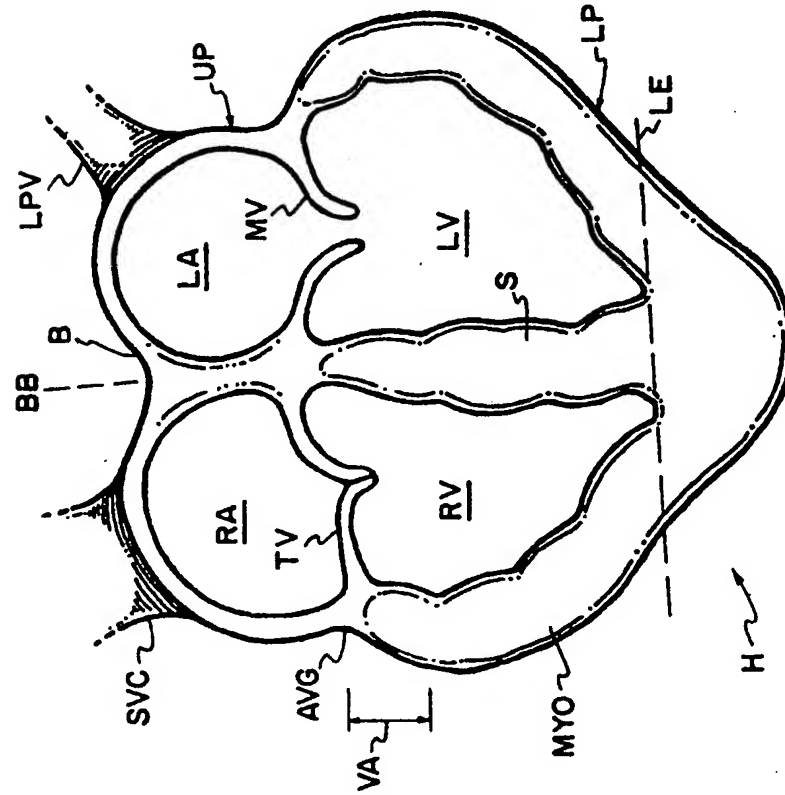
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FIG. 2

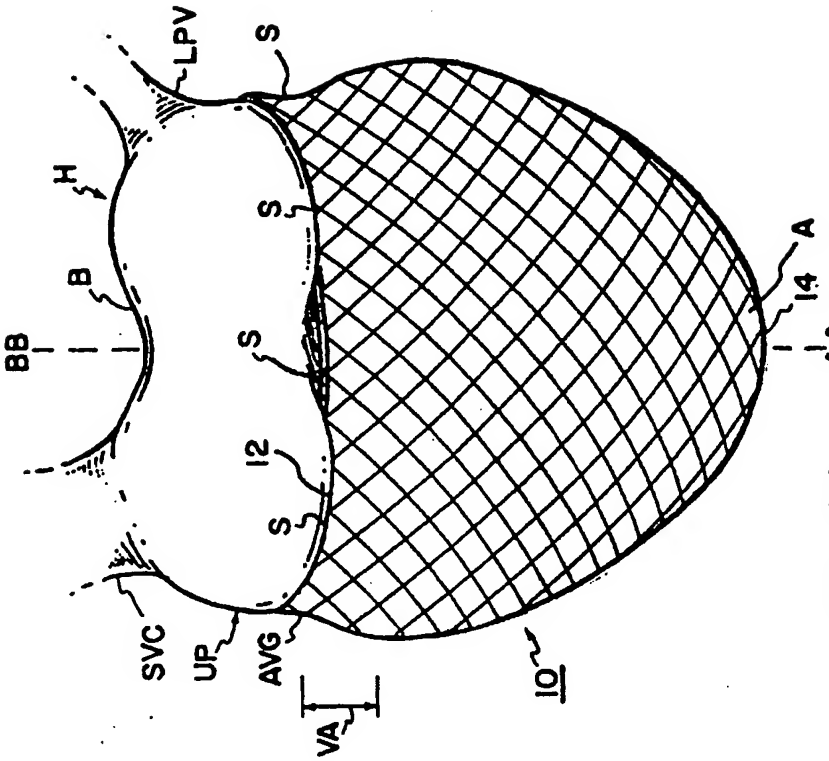


FIG. 3A

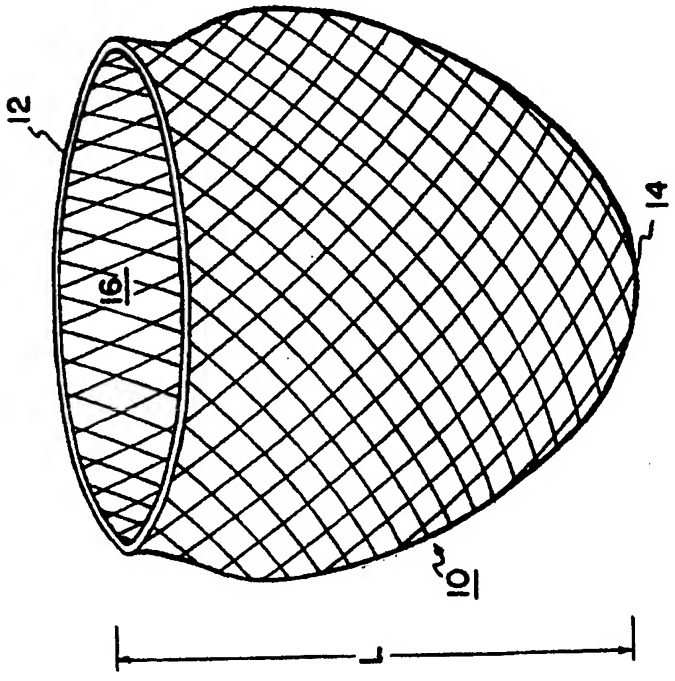


FIG. 3

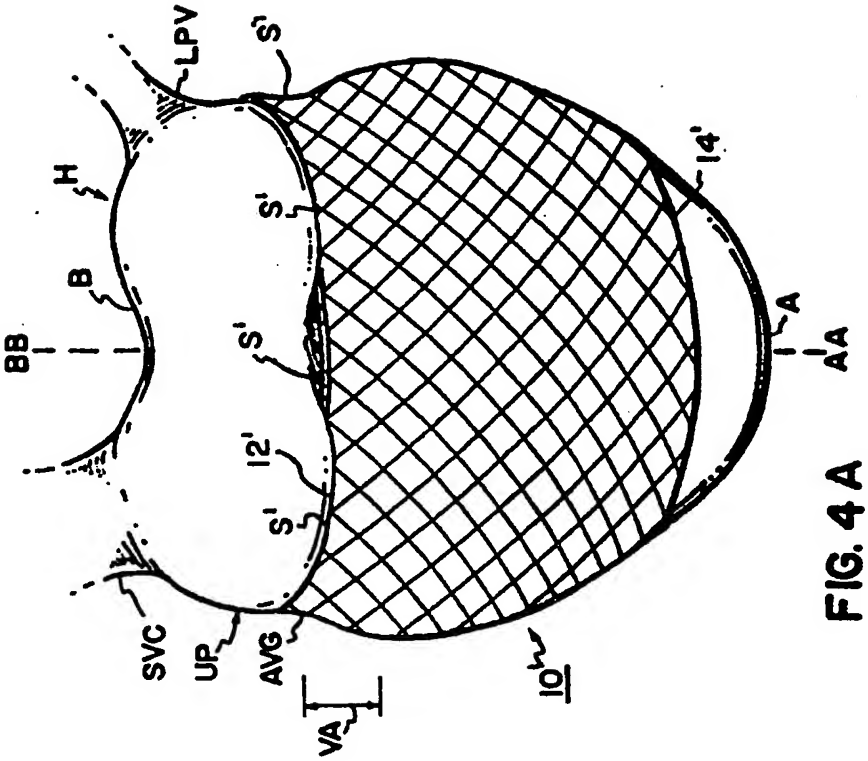


FIG. 4A

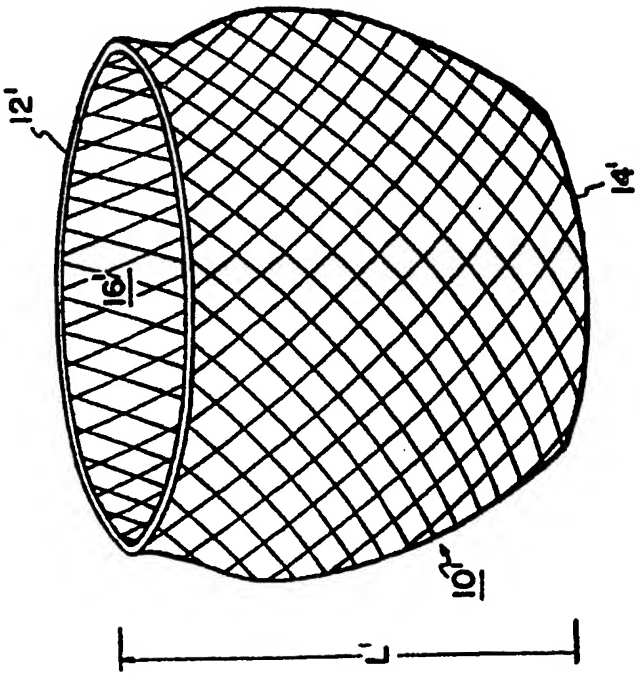


FIG. 4

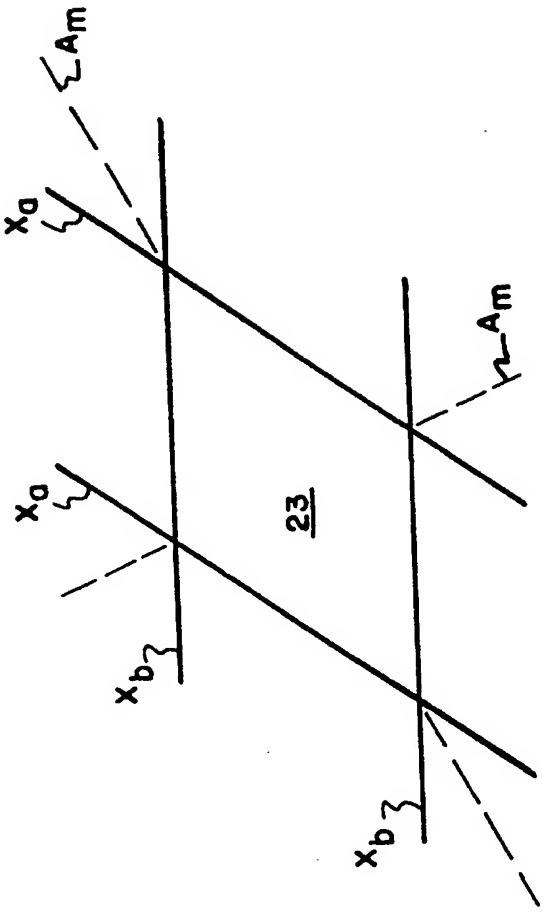


FIG. 7

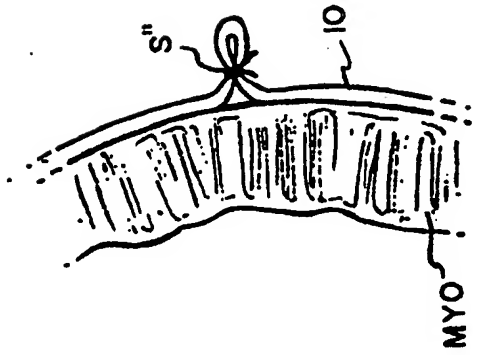


FIG. 5

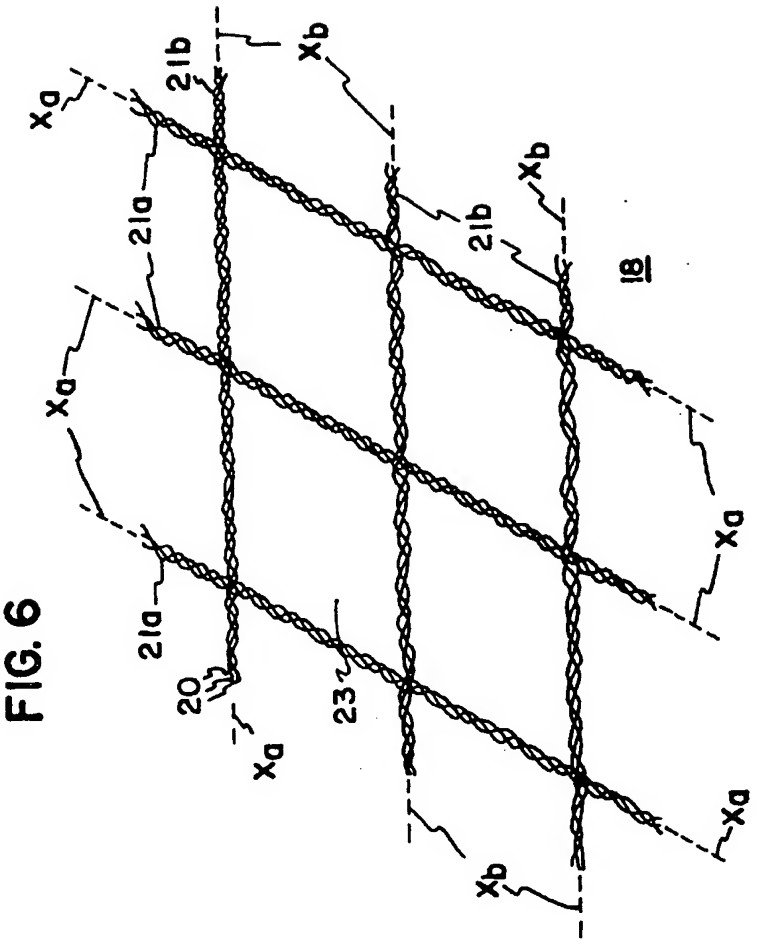


FIG. 6

FIG. 8

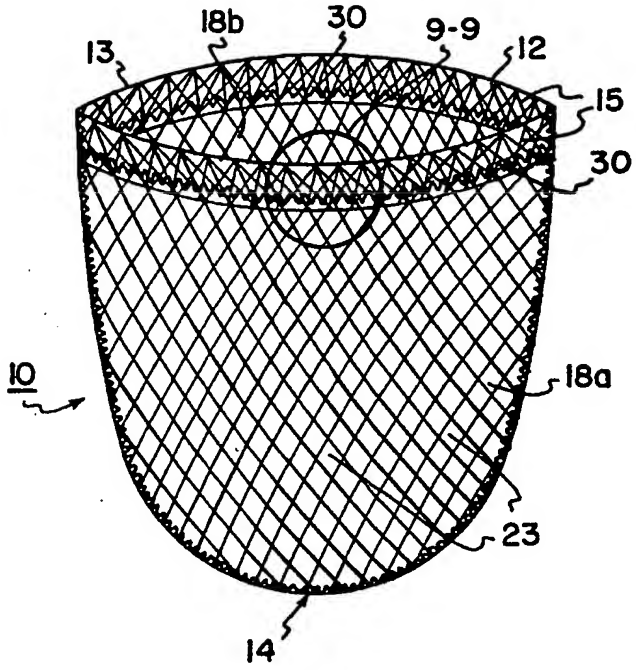


FIG. 9

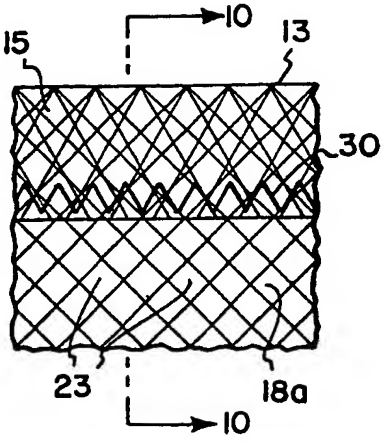


FIG. 10

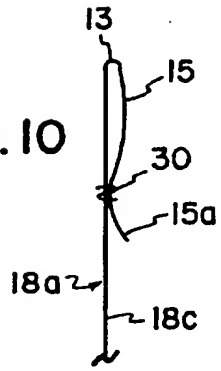


FIG. 11

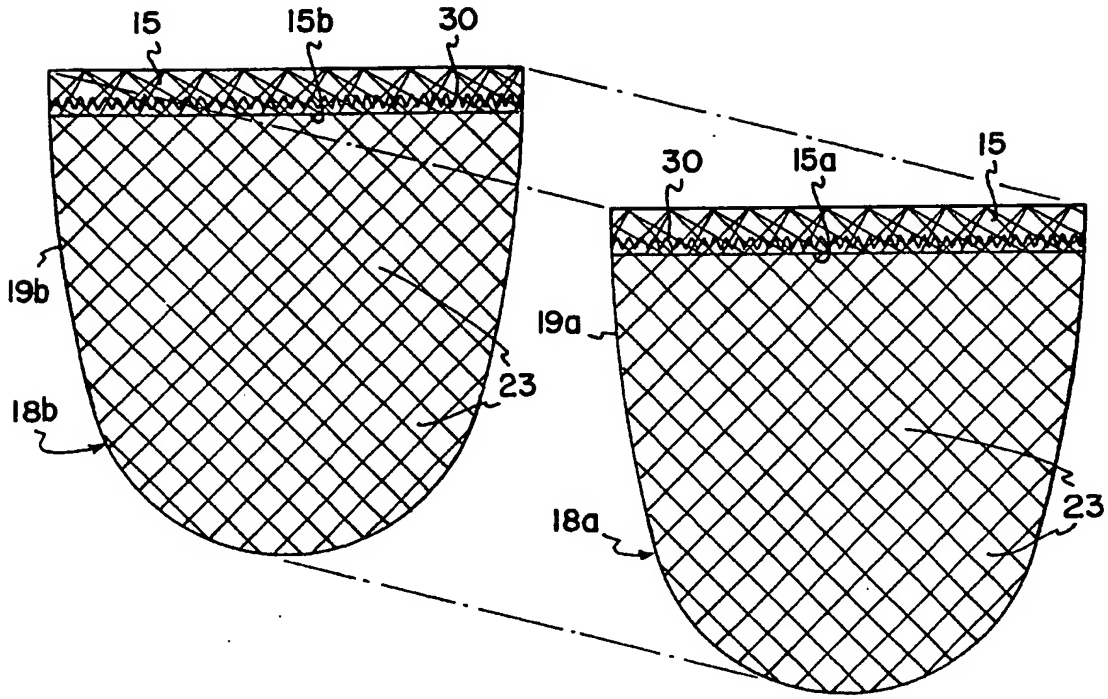


FIG. 12

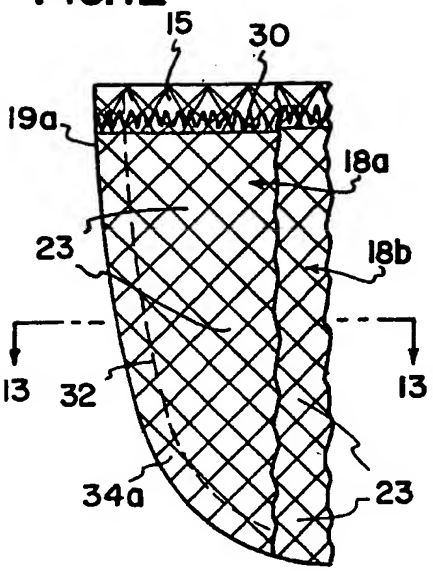


FIG. 13

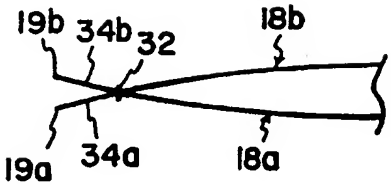


FIG. 14

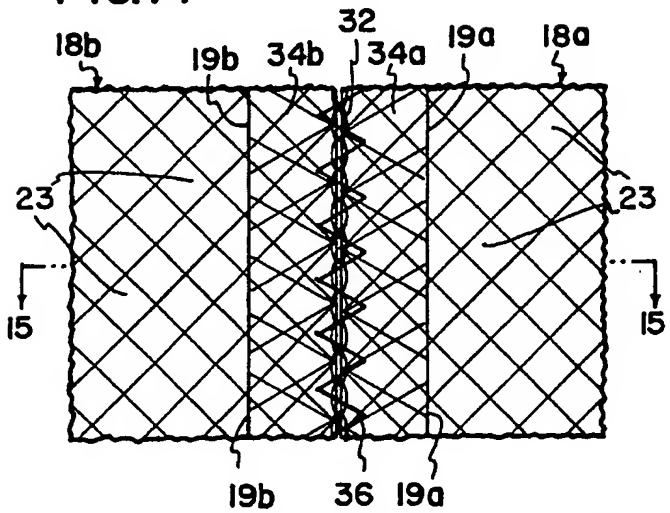
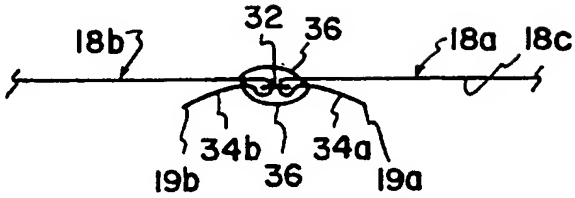


FIG. 15



INTERNATIONAL SEARCH REPORT

national Application No
PCT/US 00/02085

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 131 905 A (GROOTERS RONALD K) 21 July 1992 (1992-07-21) column 3, line 14 - line 33; figures	1,12,16
A	US 5 603 337 A (JARVIK ROBERT) 18 February 1997 (1997-02-18) column 4, line 38 - line 62; figures	1,2,12, 13,16,17
A	WO 98 58598 A (HAINDL HANS) 30 December 1998 (1998-12-30) page 8, line 2 - line 9; figures	1,2,7,12
A	US 5 702 343 A (ALFERNESS CLIFTON A) 30 December 1997 (1997-12-30) cited in the application column 4, line 31 - line 40; figures	1,12,13

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
24 May 2000	02/06/2000

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

national Application No
PCT/US 00/02085

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 256 132 A (SNYDERS ROBERT V) 26 October 1993 (1993-10-26) column 2, line 27 - line 62; claim 3; figures	1,12

1

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Information on patent family members

national Application No
PCT/US 00/02085

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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